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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,020	01/16/2004	Charles J. Davidson	1001.2280102	5771
28075 7590 02/03/2009 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420				
			EXAMINER MATTHEWS, WILLIAM H	
			ART UNIT 3774	PAPER NUMBER
			MAIL DATE 02/03/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/758,020

**Applicant(s)**

DAVIDSON ET AL.

**Examiner**

William H. Matthews (Howie)

**Art Unit**

3774

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12, 23, 25, 26 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 is/are allowed.
- 6) ☒ Claim(s) 23, 25, 26, 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Response to Arguments***

Applicant's arguments filed 8-7-07 have been considered but are not persuasive.

Regarding the rejections under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, Applicant provides support for having the transducer positioned to transmit signals through the stent's side opening but the specification fails to support the limitation "in axial and radial alignment with the side opening". In particular, "radial alignment" also encompasses a transducer positioned at the same radial distance as the side opening which was not disclosed in the specification as filed nor in the provisional application.

With regard to the rejection under 35 U.S.C. 103(a), Applicant contends each of the cited references fails to disclose a transducer in axial and radial alignment with a stent opening, nor motivation to provide such an arrangement. Examiner disagrees because the references teach the use of transducers to aid in visualization and locating for vascular procedures and having transducers placed on a vascular catheter. The additional step of aligning the opening and transducer would have been readily apparent to one of ordinary skill in the art because the purpose of the procedure is to align the opening of the stent with a branch vessel.

***Priority***

The claims receive priority benefit of parent application 09/669,060 filed September 22, 2000. The claims do not receive priority benefit of provisional application 60/155,611 filed September 23, 1999 because they are not fully supported

by the provisional application. The effective filing date of the claims is September 22, 2000.

Applicant failed to adequately provide specifics regarding the application being identical or the subject matter being fully supported by the earlier filed applications, specifically, the provisional application (60/155,611). The limitation regarding axial and radial alignment is not supported.

### ***Claim Objections***

Claim 25 objected to because of the following informalities: "an" should be amended to ---a---. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23,25,26,28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the claims to include the limitation of "stent in axial and radial alignment with the side opening" is not clearly supported in the original specification. In particular, "radial alignment" encompasses a

transducer positioned at the same radial distance as the side opening which was not disclosed in the specification as filed nor in the provisional application.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23,25,26,28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Oepen (6048361) in view of O'Connor (6398792 as cited in applicant's IDS), Solomon (5846204) and Jang et al (USPN 5,749,848 as cited in applicant's IDS).

Von Oepen discloses a stent delivery system for use in a body lumen with all the elements of the claim, but is silent to an ultrasound transducer being disposed near the catheter body distal end. See Figure 3 for catheter (30) comprising a catheter body having a distal end, proximal end, a longitudinal axis and a lumen, an expansion device (balloon) disposed near the catheter body distal end, and a stent (20) disposed over the expansion device. See Figure 2 and column 2, lines 66-67 for the stent (20) having a wall comprising struts and connectors forming multiple passageways (21) and further comprising a side hole (22) that is adapted to provide access to a side branch. O'Connor teaches an ultrasonic catheter system, which includes an ultrasound transducer. While the transducer is used for treatment of the vascular system, it is known in the art to use the transducer for location application as taught by Jang et al.

Furthermore, O'Connor teaches use of the transducer for visualization before and after an operation (column 4, lines 1-4). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the stent delivery system of Von Oepen to include an ultrasound imaging transducer disposed inside the expansion device in order to determine exactly where the diseased segment of the blood vessel begins and ends and to correctly position the stent such that the side hole is positioned at the ostium of a branch vessel. This would replace the completely separate x-ray contrast means and x-ray screen for visual monitoring used by Von Oepen for positioning the side hole, thus simplifying the procedure. The examiner contends that use of this ultrasound transducer instead of x-ray will provide the surgeon with more accurate, informative and controllable images of the diseased vessels for side hole positioning.

With regard to the housing of claims 25 and 28, Solomon teaches in Figure 1, a rotatable ultrasound catheter (100) with a transducer housing for imaging. A guidewire is accepted through the passage (114) in order to prevent unintended deflection of the transducer as it is rotated around the guidewire for three-dimensional imaging. See column 5, lines 1-14. Because the guidewire sleeve portion (108) is *integral with* the housing portion (104), the transducer housing is rightfully interpreted as including both portions (104 and 108) (column 5, lines 19-22). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of O'Connor and/or Solomon to modify the stent delivery system of Von to include a transducer housing with a passage coupled to the transducer and a guidewire disposed

in the passage. This ensures that the ultrasound transducer travels in a predetermined path around the guidewire maintained in the passage, which is configured to maintain the planar surface of the transducer substantially parallel with a portion of the guidewire that is located within the passage. The imaging device with transducer can be positioned directly over the guidewire through the passage and advantageously reduce operating time.

***Allowable Subject Matter***

Claim 12 is allowed.

***Conclusion***

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/  
Primary Examiner  
Art Unit 3774